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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,223	06/08/2006	Edith Trost Sorensen	P30040	3853

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EXAMINER	
WEBB, WALTER E	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/582,223	SORENSEN, EDITH TROST	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16 and 20-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-16 and 20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 9/10/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112--New

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 14, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The term “essentially sugar-free" in claim 7 is a relative term which renders the claim indefinite. The term "essentially sugar-free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how much sugar can be added to the composition such that the composition is "essentially” sugar-free.

2) The term "supplement" in claim 14 is a relative term which renders the claim indefinite. The term "supplement" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear how

supplement is being used in the context of the claim, such that no clear line of demarcation exists between the "supplement" and other claimed components which are also arguably "supplements" (e.g., “confectionary additives”: see claim 1; "therapeutically active agents": see claim 13).

3) Furthermore, the terms “tobacco-related” and “coffee-related” are also relative terms which render claims 21 and 22 indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear to what degree of association is necessary for a product to be "related" to coffee or tobacco.

Claim Rejections - 35 USC § 103--New

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-8, 10, 13, 20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al., (US 6,926,916).

1) Day et al. teaches a chewing gum composition (**claim 20**) comprising a polymeric surface active agent (see Abstract). The reference teaches adding an abrasive polishing material such as calcium pyrophosphate in an amount of 1% to 70% (**claims 1, 23 and 24**), and preferably from about 5% to about 50%, by weight of the

chewing gum composition (see col. 6, lines 19-39). The gum base is taught to be 28% of the composition (**claims 3, 25 and 26**) (see Examples at col. 11), and may comprise synthetic elastomers (**claim 4**) such as chicle (see col. 6, lines 40-48). The chewing gum is a confectionary, as per **claims 5 and 6**, insofar as it may comprise bulk sweeteners such as sucrose, fructose, dextrose and mixtures thereof (see col. 8, lines 8-28). The chewing gum may also be "essentially sugar-free" (**claim 7**) since it may comprise artificial sweeteners such as sorbitol and mannitol (see Id). The composition may also comprise a tooth whitening agent, such as peroxide or percarbonate, as per **claim 8**, a bicarbonate salt (**claim 10**), antimicrobial agents (**claim 13**) (see col. 9, lines 20-23 and col. 10, lines 30-32).

The prior art reference teaches the combination of features instantly claimed. However, the reference is not anticipatory insofar as calcium pyrophosphate is not disclosed as the preferred species, but its selection would have been obvious given its plain enumeration by the prior art.

2) Claims 9, 11, 14, 15, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. (*supra*) as applied to claims 1, 3-8, 10, 13, 20 and 23-26 above, and further in view of Rajaiah et al., (US 2003/0072841).

Day et al., taught above, differs from the instant claims 9, 11, 14, 15, 26, and 27 insofar as it does not teach amounts for the additional whitening agent, bicarbonate salt, or the addition of vitamin C.

Rajaiah et al. teaches a chewing gum and confection composition that inhibits buildup of plaque and other debris on teeth, thereby inhibiting gingivitis, caries and staining (see abstract). The reference teaches adding sodium bicarbonate as a carrier material in an amount from 0.5% to about 50% (see paragraph [0071]), nutrients such as vitamin C for improving conditions of the oral cavity (see paragraph [0038]), and whitening agents such as percarbonate in an amount from 0.5% to about 10% (see paragraph [0039].)

It would have been obvious to a person havening ordinary skill in the art at the time of applicant's invention to have used vitamin C in the composition of Day et al., since vitamin C is used to for improving conditions of the oral cavity, as taught by Rajaiah et al.

Where the prior art does not disclose the exact claimed values, even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Also, MPEP 2131.03 states that a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Here, Rajaiah et al. discloses a range amount for the use of percarbonate, and sodium bicarbonate in a chewing gum/confectionary composition. The artisan would have been motivated to use amounts within these ranges for the composition of Day et al., since these amounts have been determined to be sufficient for their intended use. A prima facie case of obviousness exists since the prior art

ranges overlap or are close enough to the instant claimed ranges that one skilled in the art would have expected them to have the same properties.

3) Claims 1, 3-7, 13, 14, 20, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza et al., (EP0309414).

Cavazza et al. teaches a chewing gum composition (**claim 20**) endowed with antitartar activity, the composition comprising a chewing gum base and an amount of neutral and acidic alkali and alkaline-earth metal polyphosphates as active principle (see Abstract). **Calcium pyrophosphate** is among the particularly preferred active principles (see page 2, lines 58-60). It was found that the optimum amount of polyphosphates comprise between 0.01% and 5% by weight of the composition (**claims 1 and 23**) (see page 3, lines 54-55). Example 1 shows a composition comprising 28% NSTA synthetic chewing gum base (**claims 3, 4, 25 and 26**), mannitol, spearmint oil, sorbitol (sweetener as per **claim 6**), sodium fluoride, saccharin, menthol, clycerol, potassium sorbate (see bottom of page 3 to top of page 4). The example is a confectionary (**claim 5**) insofar as it comprises artificial sweeteners i.e. sorbitol, mannitol, and saccarin. The example is also sugar-free, as per **claim 7**, and comprises an anti-microbial agent, as per **claim 13**, insofar as it comprises spearmint oil. Example 6 comprises a supplement, as per **claim 14**, insofar as it comprises zinc citrate (see Example 6 at pg. 5).

The prior art reference teaches the combination of features instantly claimed. However, the reference is not anticipatory insofar as calcium pyrophosphate is not

disclosed as the preferred species, but its selection would have been obvious given its plain enumeration by the prior art.

4) Claims 8-11, 15, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza et al. (*supra*) as applied to claims 1, 3-7, 13, 14, 20, 23, 25 and 26 above, and further in view of Rajaiah et al., (US 2003/0072841).

Cavazza et al., taught above, differs from the instant claims 8-11, 15, 27 and 28 insofar as it does not teach adding an additional whitening agent, sodium bicarbonate, or vitamin C to the chewing gum composition.

Rajaiah et al. teaches a chewing gum and confection composition that inhibits buildup of plaque and other debris on teeth, thereby inhibiting gingivitis, caries and staining (see abstract). The reference teaches adding sodium bicarbonate as a carrier material in an amount from 0.5% to about 50% (see paragraph [0071]), nutrients such as vitamin C for improving conditions of the oral cavity (see paragraph [0038]), and whitening agents such as percarbonate in an amount from 0.5% to about 10% (see paragraph [0039].)

Generally, it is also *prima facie* obvious to select a known material based on its suitability for its intended use (see MPEP 2144.06). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function (see Id).

Thus, it would have been obvious to a person havening ordinary skill in the art at the time of applicant's invention to have used vitamin C, sodium bicarbonate, and/or

percarbonate in the composition of Cavazza et al., based on their suitability for their intended use, as taught by Rajaiah et al.

5) Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza et al. (*supra*) as applied to claims 1, 3-7, 13, 14, 20, 23, 25 and 26 above, and further in view of Gibbs et al., (International Journal of Food Sciences and Nutrition 1999.)

Cavazza et al. differs from the instant claim 12 insofar as it does not teach encapsulation of at least one additive and calcium pyrophosphate.

Gibbs et al. teach encapsulation of food ingredients such as flavoring agents, acids, bases, antioxidants, sweeteners. (See abstract.) Encapsulation is useful to enhance the stability and maintain viability of foods and also to allow for site-specific and or stage specific release of ingredients. (See ibid.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to encapsulate at least one additive and the calcium pyrophosphate of Cavazza et al. since doing so would, for example, prevent loss of flavor, and allow for a controlled release of the calcium pyrophosphate.

6) Claims 16 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza et al. (supra) as applied to claims 1, 3-7, 13, 14, 20, 23, 25 and 26 above, and further in view of Lutzen (US 5,470,566).

Cavazza et al. differs from the instant claims 16 and 29-31 insofar as it does not teach adding urea to its chewing gum composition.

Lutzen et al. teaches a solid, oral anticariogenic composition in the form of a chewing gum or lozenge containing as dental plaque acid-neutralizing ingredient urea in an amount from 0.5% by weight to 80% by weight, based on the total weight of the composition (see Abstract). The composition is used to neutralize acid in the dental plaque subsequent to eating and drinking (see col. 5, lines 2-14). The reference teaches a chewing gum comprising 0.8-4% by weight of urea (see col. 7, lines 47-55).

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to add the urea of Lutzen to the chewing gum of Cavazza et al. since urea neutralizes plaque acids. The artisan would have been motivated to reduce the risk of dental carries subsequent to eating and drinking, as taught by Lutzen.

Response to Arguments

Applicant's argument with regard to use of Rajaiah as a primary reference is moot in view of the withdrawal of Rajaiah as a primary reference. However, applicant's arguments with respect to unexpected results will be addressed.

Applicant argues that the use of 0.5 to 9% of calcium pyrophosphate as an **abrasive agent** has improved stain removal and stain inhibition over the more commonly used calcium carbonate ($CaCO_3$). Applicant's data can be found in the specification at pages 16-22. Table 1 of page 16, compares 4.5% calcium carbonate, 4.5% calcium pyrophosphate, and 6.5% calcium pyrophosphate. The results indicate

that calcium pyrophosphate at either percentage produced a greater reduction of stain on enamel. Similar results were shown in Table 2 at page 18. For the comparative tests of Tables 3-6 it is noted that the percentage of calcium pyrophosphate was higher (6.5%) than the percentage of calcium carbonate (4.5%). No explanation was given for this difference. However, these results are not unexpected since calcium carbonate has been recognized as a "poorer" abrasive agent compared to calcium pyrophosphate. For the purpose of rebutting applicant's arguments that the results of the comparative data of calcium carbonate and calcium pyrophosphate are unexpected, the Examiner cites Putt et al. (J Dent Res 1980). Putt et al. compared the polishing properties of seven different polishing agents on human enamel and bovine enamel, including calcium pyrophosphate and calcium carbonate. The data at the Table shows calcium pyrophosphate having a polish score of 83+/-2 for human enamel, and calcium carbonate having a polish score of 32+/-4. Calcium carbonate was recognized as a "poorer polishing agent" (it resulted in larger differences in the polish score between the two types of enamel) (see right column, lines 8-10). The artisan would therefore reasonably expect calcium pyrophosphate to outperform calcium carbonate in a comparative test for removing stains from enamel.

Even if applicant's data showed an unexpected result, the instant claims are not commensurate in scope. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed

to see if the results occur over the entire claimed range. Here, the instant claims recite a broad range for the amount of calcium carbonate e.g. between 3% and 8% (claim 1) while the data tests two different percentages 4.5% and 6.5%. It is not clear whether the results can be seen over the entire claimed range. It is also noted that, while the tests were performed on a chewing gum composition, the claims are not limited to a chewing gum composition.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612